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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Masaki BABA et al

Group Art Unit: 1796

Serial Number: 10/541,746

Examiner: Michael Pepitone

Filed: July 8, 2005

For: SILICONE-CONTAINING OCULAR LENS MATERIAL WITH HIGH  
SAFETY AND PREPARING METHOD THEREOF

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir,

Tsuyoshi Watanabe residing at c/o MENICON CO., LTD.,  
Central research laboratories, 1-10, Takamoridai 5-chome, Kasugai-shi,  
Aichi 487-0032, JAPAN, duly declares and states:

1. That he graduated from School of Materials Science of Japan Advanced Institute of Science and Technology (JAIST), Ishikawa, Japan, in the year 1994;
2. That he has been employed since 1991 by MENICON CO., LTD.
3. That since 1991 he has been engaged in Material Research & Development department.
4. That he is one inventor of the above-identified patent application and so familiar with the above-identified patent application

and the Office Action thereto mailed August 30, 2010.

5. That he conducted the experiments described below in order to demonstrate that not only a pyrrolidone derivative (B) selected from the group consisting of 1-alkyl-3-methylene-2-pyrrolidone, 1-alkyl-5-methylene-2-pyrrolidone, and 5-alkyl-3-methylene-2-pyrrolidone, but also a N-substituted acrylamide (D) has an effect on the decreased residual monomer, in other word, the improved copolymerizability.

#### I. Experimental Examples A to D

Ocular Lens components shown in Table 1 were mixed and injected into a mold (made of a polypropylene; corresponding to a contact lens with a diameter of about 13 mm and a thickness of 0.1 mm) having a contact lens shape. Ethylene glycol dimethacrylate (EDMA) and 2-hydroxy-2-methyl-propiophenone were used as crosslinking agent and initiator, respectively according to Examples of the instant application. Then, photo polymerization was carried out by irradiating UV light on the mold for 20 minutes to obtain polymers having a contact lens shape.

Table 1

Experimental Example (Corresponding Example of the instant application)	A (EX.17)	B	C (EX.1)	D
<u>Monomer</u>				
(C) TRIS	25	25	27	27
(A) Macromer A1	25	25	23	23
(D) DMAA	12.5	-	10	-
(B) 1,3-MMP	37.5	50	40	50

TRIS: Tris(trimethylsiloxy)silylpropyl methacrylate

Macromer A1: Macromonomer (A1) prepared according to the preparation method described in the specification of the instant application

DMAA: N,N-dimethylacrylamide

1,3-MMP: 1-Methyl-3-methylene-2-pyrrolidone

## II. Evaluation of the amounts of residual monomers

After polymerization, a lens taken out from a mold was immersed in acetonitrile and the extraction of residual components was carried out. The extract was analyzed with HPLC, and the residual rates of monomers based on mixed amounts were calculated with respect to TRIS and 1,3-MMP, respectively. The residual rates S1 (%) for the amount of respective monomer used and the residual rates S2 (%) for the total amount of a lens were calculated as the same manner in section of "Determination of residual monomers (HPLC)" in the specification of the instant application.

## III. Results

The results evaluating the amounts of unreacted residual monomers TRIS and 1,3-MMP in the polymer were shown in Table 2. Experimental Examples B and D are corresponding to Experimental Examples A and C in which DMAA is substituted by 1,3-MMP, respectively. In Experimental Examples A and C which employs DMAA, the residual rates of TRIS are form about one-half to one-third of those of Experimental Examples B and D, respectively. Similarly, the residual rates of 1,3-MMP are very low in Experimental Examples A

and C compared with Experimental Examples B and D.

Table 2

Experiment Example (Corresponding Example of the instant application)	A (EX.17)	B	C (EX.1)	D
<u>Residual rates of TRIS (%)</u>				
S1 (for the amount of TRIS)	1.6	4.8	2.3	4.8
S2 (for the total amount of Lens)	0.4	1.2	0.6	1.3
<u>Residual rates of 1,3-MMP (%)</u>				
S1 (for the amount of 1,3-MMP)	0.2	4.1	0.5	4.2
S2 (for the total amount of Lens)	0.1	2.0	0.2	2.1

#### IV. Conclusion

It has been already described in the specification of the instant application that N-MMP is excellent in polymerizability and copolymerizability with a silicone monomer compared with N-VP (see Examples 1 to 3 and Comparative Example 1). The above results indicate that the use of a N-substituted acrylamide (D) (DMAA) can lead to the more improved copolymerizability and the effectively decreased residual TRIS and N-MMP.

Therefore, it can demonstrated that not only a pyrrolidone derivative (B) selected from the group consisting of 1-alkyl-3-methylene-2-pyrrolidone, 1-alkyl-5-methylene-2-pyrrolidone, and 5-alkyl-3-methylene-2-pyrrolidone, but also a N-substituted acrylamide (D) has an effect on the decreased residual monomer, in other word, the improved copolymerizability.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

This 26th day of November, 2010

by

Tsuyoshi Watanabe

Tsuyoshi WATANABE

We, the undersigned witnesses, hereby acknowledge that Tsuyoshi WATANABE is personally known to us and did execute the foregoing Declaration in our presence on:

Date: November 26, 2010      Witness Shigeyasu Nagai

Date: November 26, 2010      Witness Koji Otani